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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,104	04/28/2005	Yong Kwee	053466-0401	5920

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,104	KWEE ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,12 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *24 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 12, 23, 25 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Kwee et al.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2009 has been entered.

2. Claims 1, 3, 12, and 23-32 are pending. New claim 32 has been added. Claims 2, 4-11, and 13-22 have been cancelled. Claims 24 and 26-31 have been withdrawn from consideration as being drawn to non-elected inventions. No claims have been amended.

3. Claims 1, 3, 12, 23, 25 and 32 are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 12, and 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27) is maintained.

The response states that immune reactions in the immunotherapy of cancer include an immune reaction by an antibody reaction and immune reaction by T cells, and these reactions are completely different in their mechanisms for causing an immune reaction. The immune reaction of the present invention is one caused by T cells. On the other hand, Chiriva-Internati does not describe a viral vector which expresses an HM 1.24 protein that is directly pulsed on dendritic cells. The Ohtomo reference merely suggests that an HM1.24 antigen may be used for immunotherapy using antibody reaction, and this reference does not suggest at all immunotherapy using T cell reaction, of which the mechanism is completely different from that of immunotherapy using antibody reaction. The response states that the Chiriva-Internati reference suggests the disadvantage of direct use of HM1.24 protein or HM1.24 peptide, which have a rather short half-life and as such Chiriva-Internati specifically teaches away from this combination.

Applicant's arguments have been carefully considered but are not persuasive. Chiriva-Internati et al. teach that pulsing dendritic cells via an adeno-associated viral vector/HM1.24 recombinant generates rapid, significant cytotoxic T lymphocytes and interferon activity against multiple myeloma and synthetic HM1.24-positive autologous targets (see abstract). Therefore, Chiriva-Internati et al. have demonstrated that HM1.24 antigen expressed by the viral vector and presented by the dendritic cells are capable of inducing significant cytotoxic T cell response. While Chiriva-Internati et al. do not teach pulsing dendritic cells directly with HM1.24 antigen, it would have being obvious to do so in view of the teaching of Treon et al. that dendritic cells can be pulsed

with whole tumor antigen, naked DNA or whole tumor RNA for treating multiple myeloma (MM) (see page 604, left column). The state of the art at the time the instant invention was made is that treating cancer including myeloma (MM) using dendritic cells pulsed with tumor antigen, viral vector encoding a tumor antigen was well known. Applicant's arguments of teaching away are not persuasive. "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). For these reasons, the rejection is maintained.

5. The rejection of claims 1, 3, 12, 23, and 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27), further in view of WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidence by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS) is maintained.

Applicants presented the same arguments as for the prior 103(a) rejection, these arguments are not persuasive for the same reasons set forth above (see paragraph 4).

New Grounds of Rejection

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3, 12, 23, 25 and new claim 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8 (Suppl 2): S27), WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidenced by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS)), and further in view of Thurner et al. (J. Exp. Med., 1999, 190(11): 1669-1678, IDS).

The teachings of Treon, Ohtomo, Chiriva-Internati, WO 200177362 and Porgador et al. have been set forth before as they apply to claims 1, 3, 12, 23 and 25 (see office actions mailed on 4/24/2008 and 4/15/09).

The above references do not disclose that the vaccine is prepared by a method comprising a step of accomplishing the maturation. However, these deficiencies are made up for in the teachings of Thurner et al.

Thurner et al. teach a method of making a cancer vaccine comprising tumor antigen pulsed dendritic cells, the method comprises pulsing dendritic cells with tumor peptide Mage-3A1 and harvesting mature DCs on day 7 (see page 1670, column 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make the cancer vaccine comprising HM1.24 protein or peptide pulsed dendritic cells using the method of Thurner in view of the teachings of Thurner. One would have been motivated to do so because the vaccine prepared by Thurner was shown to expand tumor specific CTLs and elicit regressions even in advanced cancer. Moreover, one of ordinary skill in the art would have a reasonable expectation of success to make the cancer vaccine comprising HM1.24 protein or peptide pulsed dendritic cells using the method of Thurner because Thurner et al. teach such method.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643